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Cardiac Implantable Electrical Devices: Bioethics and Management Issues Near the End of Life

Freddy M. Abi-Samra, MD

Director, Cardiac Electrophysiology Laboratories, Department of Cardiology, Ochsner Clinic Foundation, New Orleans, LA

ABSTRACT

Cardiac implantable electrical devices (CIEDs) are extremely sophisticated modern devices that provide patients with many beneficial effects, including increased survival and enhanced quality of life. CIEDs, however, may complicate and unnecessarily prolong the process of dying from terminal illnesses. A rational plan for CIED deactivation near the end of life should therefore be carefully drawn up well in advance by the patient in concert with loved ones and treating physicians.

INTRODUCTION

In an era when the very definition of death is subject to debate (hence the terms brain death, vegetative state, cardiac arrest), it is no surprise that societal and personal responses to the process of dying cover a very wide spectrum of views shaped by emotions, religious beliefs, personal and social ethics, family values, human dignity concerns, and jurisprudence.[1]

The attitudes of physicians taking care of terminal patients are further influenced by access to medical knowledge and technologies that allow constant interference with the timeline and the succession of events preceding the inevitable result.

Address correspondence to
Freddy M. Abi-Samra, MD
Department of Cardiology
Electrophysiology
Ochsner Clinic Foundation
1514 Jefferson Highway
New Orleans, LA 70121
Tel: (504) 842-4036
Fax: (504) 842-5823
Email: fabisamra@ochsner.org

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The simple view is that physicians' core mission is to fight disease and death. We are trained to win countless battles against disease in a war that we cannot win; we are conditioned to lead the charge to keep death at bay for as long as we can face the challenge and marshal our forces and resources. Every victory is its own reward, yet each exacts a price—one that may often be too much to bear for the patient, his or her family, caretakers, society at large, and, not insignificantly, the treating physicians.

Until recent medical advances changed the playing field, dying drew a relatively short arc: A major illness occurred, and death followed within a few hours (eg, heart attack), days (eg, bacterial pneumonia), or weeks (eg, acute leukemia). Even childbirth was a very dangerous, often lethal, seminal event for both mother and newborn.

Progress in medical therapies has allowed cardiologists to spare many lives from untimely demise. As a result, the process of dying has been modified from one that is generally acute or sudden, unforeseeable in its timing but predictable in its simplicity, to one that remains, of course, inescapable but only vaguely foreseeable in its timing and often discouragingly predictable in its complexity.

HEART OF THE MATTER

Unlike obstetricians, cardiac electrophysiologists generally deal with patients who chronically face the risk of imminent death. Because death is ultimately inevitable, our preparations for battle must include plans for retreat, cease fire, and graceful defeat.

For electrophysiologists, this is a constant practice issue, as we spend much of our energy implanting and maintaining devices that are designed to prevent—nay, eliminate—sudden cardiac death. Three types of cardiac implantable electrical devices (CIEDs) are in widespread use: pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. CRTs are one of two types: CRT pacers (CRT-P) or CRT defibrillators (CRTD).

Pacemakers are generally prescribed to improve quality of life rather than to prevent sudden cardiac death. Defibrillators, on the other hand, are prescribed to abort potential episodes of sudden cardiac death

related to ventricular tachycardia (VT) or fibrillation (VF).[2-5] CRT devices are prescribed to help alleviate heart failure symptoms.[6-10]

Once implanted, these devices become integral to a person's makeup; because of their durability, they typically are expected to outlast their recipient, thus potentially interfering with the patient's process of dying.

EFFECT ON DYING

Terminal patients often develop conditions (heart failure, electrolyte imbalance, sepsis, hypoxia, etc) that increase the likelihood that their ICD will deliver shock therapy. In fact, in the last weeks of their lives, approximately 20% of ICD recipients sustain painful shocks[11] that can be psychologically disturbing to them and their loved ones and do not prolong a life of acceptable quality. A functioning ICD will always respond to a VF event and often successfully resuscitate a patient who may, in fact, have welcomed VF as a prompt, painless path to death. Instead, he or she is now doomed to linger for a few more hours, days, or weeks, breathless and suffering. This result is inconsistent with comfort care goals, and it is therefore appropriate to consider device deactivation when death is judged to be near.

Most physicians who care for patients with CIEDs have participated in device deactivations. However, the understanding of device deactivation varies among caregivers, patients, and families alike[12,13] (see the paper by Lisa Tompkins in this issue).

A single tertiary center study by Kramer et al[12] surveyed physicians about their clinical experience, legal knowledge, and ethical beliefs regarding the withdrawal of CIED therapy in comparison to withdrawal of other life-sustaining therapies such as mechanical ventilation, dialysis, and feeding tubes. Physicians were consistently less comfortable discussing CIED deactivation compared to other life-sustaining therapies. Furthermore, a significant minority characterized CIED deactivation as physician-assisted suicide or euthanasia (28% when pacemaker-dependent patients were involved and 11% for ICD patients).[12]

Kramer and colleagues[13] have shown that patients have similar views. In a nearly identical survey, they asked patients with hypertrophic cardiomyopathy (at a high risk of requiring CIEDs) about their opinions regarding CIED deactivation. Similar to physicians, patients regarded CIED deactivation as morally different from the cessation of mechanical ventilation or dialysis, with 29% characterizing pacemaker deactivation as assisted suicide or euthanasia (17% for ICD deactivation).

Another notable finding from this study involved the lack of communication with clinicians about the end of life. Only 4% of patients had provided written advance directives regarding their CIED. An additional 21% had discussed their views regarding their CIEDs with a designated health provider.[13]

CONSENSUS STATEMENTS

With the geometric expansion of the use of CIEDs in the developed world, experts on both sides of the Atlantic[14,15] have published consensus statements on the management of CIEDs in patients nearing the end of life or requesting withdrawal of therapy.

In the United States, the Heart Rhythm Society devised recommendations based on the following ethical, legal, and religious principles:[14]

- A patient or his/her legally defined surrogate has the legal right to refuse or request the withdrawal of any medical intervention regardless of the status of illness and regardless of whether the treatment is essential to life prolongation.
- The right to refuse or request withdrawal of treatment is a personal right and is not influenced by the type of treatment in question (ie, CIEDs).
- Ethically and legally, there is no difference between refusing the institution of CIED therapy and requesting its withdrawal.
- Legally, carrying out a request to withdraw life-sustaining therapy is neither physician-assisted suicide nor euthanasia. This legal concept applies equally to CIED therapy.
- In religious belief systems, the distinction between letting life go and taking life is important. Cessation of CIED therapy is intended to discontinue unwanted treatment and allow death to proceed naturally—**not** to terminate the patient's life.
- In case of moral, ethical, or religious conflict between patient and provider, a reluctant clinician cannot be compelled to participate in legally permissible CIED deactivation. Neither can the clinician abandon the patient, but should instead involve a colleague who is willing to carry out the patient's wishes.

Because decisions regarding treatment discontinuation are always difficult in the heat of emotions surrounding end-of-life illness, those discussions should occur well in advance; in fact (especially for potential recipients of ICDs), they should occur as early as the consent process before the implant. Patients should know that ICDs may complicate the process of dying and that eliminating the risk of sudden cardiac death increases the likelihood of dying from competing health risks[16] (mostly congestive heart failure, but also other terminal illness such as cancer).

The European consensus recommendations are based on a similar perspective with the exception that

interventions (ie, CIED deactivation) must be carried out in accordance with local national laws. For instance, in some European countries, it is illegal to deactivate a pacemaker but not an ICD.

HOW TO DEACTIVATE CIEDS

CIED deactivation is generally performed noninvasively and painlessly using a computer/radiofrequency interface. Features that can be deactivated include

- Shock therapy
- Antitachycardia pacing (ATP)
- CRT therapy

These features can be deactivated with a simple on/off switch.

Pacing, on the other hand, is not always as straightforward because few devices offer an ''off'' option. However, device pacing outputs and modes can generally be modified so the delivered therapy becomes ineffective.

Differences Between ICDs, Pacemakers, and CRT Devices

Turning off painful shock therapy near the end of life is an easily understood and minimally controversial intervention.

The decision to turn off painless ATP is not as simple to make. In patients with terminal conditions (eg, end-stage heart failure, disabling cardiac conditions), turning off ATP seems reasonable because any fast VT can lead to sudden cardiac death, which would curtail prolonged suffering. On the other hand, withholding ATP for the treatment of nonfatal (slow) VT (< 160 bpm) may lead to aggravated symptoms of organ failure and therefore more suffering.[17,18] For patients with slow VT, it would then seem reasonable to continue ATP without back-up shock therapy (keeping in mind that properly programmed ATP can cause VT acceleration in 2%-4% of instances).[19]

Deactivation of pacing therapy requires much more thought. The benefits of antibradycardia pacing are threefold:

1. Preventing sudden cardiac death in patients with sinus node dysfunction (rarely) or complete heart block without any escape rhythm (pacer-dependent patients)
2. Preventing syncopal or near syncopal spells in patients who have existing but unreliable escape rhythms
3. Preventing general constitutional symptoms resulting from reliable but slow heart rates (fatigue, malaise, shortness of breath, etc)[20-22]

Patients who are completely pacer dependent make up a minority of patients receiving CIEDs. Deactivation in these patients would provide the intended result of shortening an uncomfortable dying process. Unfortunately, the consequences of deactivation in this scenario are so immediate that death would result in a matter of minutes, placing a great psychological burden on the provider, who must be completely at ease with the concept that his or her actions are not tantamount to assisted suicide or euthanasia.

In contrast, deactivating pacing in patients whose conditions coincide with 2 or 3 above is problematic at best, cruel at worst, and in most cases would not seem to promote the goals of comfort care.

Finally, issues with CRT are similar to issues with antibradycardia pacing in nondependent patients. Effective CRT alleviates symptoms of heart failure, and withdrawing such therapy would in many cases simply increase patients' discomfort in their final days. One exception may be when class IV heart failure symptoms are so intractable that resultant death is imminent. In this scenario, turning off CRT may accelerate the dying process while appropriately shortening the period of breathless suffering.

The Physician's Stake

The patient's rights, beliefs, and autonomy guide the overall principles in deactivation, but what about situations in which the physician and not the patient sees hope and relies on CIEDs as a bridge to more advanced therapies? What about situations where patients request a full-court press treatment of their medical conditions and get their care providers involved in complex, work intensive, psychologically taxing, financially costly, apparently effective therapy? What if they later refuse the interference of the deus ex machina–type treatment of ICDs for any intervening, potentially lethal, yet easily reversible conditions such as VF?

Is the patient's right to die on his or her terms absolute, or does it come with social dues and responsibilities? Although the answer to this question is philosophically complex, I believe that from a Hippocratic point of view, the patient's right to refuse certain types of care is absolutely autonomous. As physicians, our only stake in these decisions should be to dispassionately discuss, advocate, listen, and provide comfort.

ILLUSTRATIVE PATIENT CASES

In my long career, I have cared for tens of thousands of patients and implanted thousands of CIEDs. The following three cases are drawn from my patient population. They illustrate the benefits and shortcomings of CIEDs.

Mr. A

I first met Mr. A in 1989, just after a failed coronary artery bypass graft surgery. His left ventricular ejection fraction (LVEF) was 20% at the time. Yet with extensive medical therapy and a daily exercise regimen, he maintained class I functionality. In May 2000, after a screening electrophysiology study, I recommended and then implanted a dual-chamber ICD for inducible VT. Mr. A had agreed to the electrophysiology study and ICD after 2 weeks of forethought.

In 2002, the discovery of a lingual squamous cell carcinoma started a long series of surgical interventions and irradiation therapy.

In March 2005, prostate cancer was diagnosed. Multiple surgeries affected his stamina only temporarily, and he remained comfortable and independent, all the while caring for his disabled wife. In 2007, at age 72, he was still taking long daily walks on his treadmill (3 miles at 3.5 mph).

On July 21, 2008, he underwent yet another extensive oral surgery. Three weeks later, he received his first ICD shock for the treatment of a life-threatening spontaneous VT. He was now also in heart failure and atrial fibrillation with fast ventricular response. The latter required the addition of amiodarone to his medication regimen. This in turn caused him to become increasingly pacemaker dependent, requiring further manipulation of ICD programming to avoid right ventricular pacing.

The development of a spontaneous left bundle branch block in late 2009 resulted in marked worsening of his congestive heart failure. This was tended to in February 2010 by surgically upgrading his ICD to one with CRT capabilities.

As a result, his congestive heart failure symptoms abated, and dyspnea was no longer an issue. He could conduct his daily living activities but continued to have severe limitations related to his cancer (weight loss, malnutrition, inability to eat and talk intelligibly, placement of an ambulatory percutaneous endoscopic gastrostomy feeding tube).

Although he seemed to be taking his symptoms in stride, he was obviously markedly diminished and suffering the effects of many illness and therapy tribulations.

In November 2010, he declined further treatment for yet another (pelvic) mass discovered a few weeks earlier. His ICD shock therapy was turned off, and he went to hospice care, where he passed away 3 months later.

Overall, a decision to implant a CIED in 2000 resulted in a life-saving intervention 8 years later but also allowed Mr. A to continue seeking and receiving less than ideal and burdensome cancer treatments for another 2½ years. The CRT-upgraded CIED further provided another year of survival with an improved but clearly still diminished quality of life.

Were these CIED contributions worthwhile or even harmless? Only Mr. A could really have answered this question. Interestingly, although I broached the subject with him on several occasions, Mr. A never clearly articulated his views regarding CIED therapy up to the day the ICD was finally turned off.

Mr. B

Mr. B's story follows an analogous but somewhat different path. A single-chamber ICD implanted in 1996 (for clinical VT, ischemic cardiomyopathy, LVEF of 15%) repeatedly treated highly symptomatic VT recurrences with ATP and shock therapy. Sick sinus syndrome resulted in an upgrade to a dual-chamber pacing ICD in September 2000. In 2006, inappropriate shocks were delivered for atrial fibrillation, necessitating atrioventricular nodal ablation and upgrade to CRT. As a result of the ablation, the treatment of his congestive heart failure remained effective enough that he was able to safely undergo repeat total left hip replacement in February 2010.

In August 2010, when Mr. B was age 80, doctors found a left pelvic mass caused by a large B cell lymphoma. Chemotherapy ensued, and when his ICD battery required replacement, Mr. B was eager to undergo the surgery, which was completed in November 2010.

Mr. B's lymphoma progressively worsened, and organ failures complicated treatment. He decided to forego further chemotherapy. The ICD was reprogrammed to provide pacing, CRT, and ATP, but not shock therapy. Mr. B lived out his remaining 2 months of life in hospice care unburdened by the threat of ICD shocks.

All during Mr. B's 15-year association with his CIED, he and Mrs. B were very grateful for all the therapies that it provided. He was justified in feeling that it both improved his quality of life and extended his longevity. Furthermore, except for an occasional unnecessary shock, the CIED did not intrinsically cause pain or prolong his ultimate death journey. After receiving the full benefits of ICD therapy for 15 years, Mr. B wisely decided to reprogram the features of his device during his last, losing battle with lymphoma.

Mr. C

Mr. C was a 75-year-old lawyer, a recipient of a single-chamber ICD in September 2007 (for ischemic cardiomyopathy, ejection fraction of 25%), who enjoyed an active and fulfilling lifestyle until he presented in September 2010 with an ICD shock that terminated an episode of VT. Over the next

6 weeks, he developed VT storms (recurrent VT/VF) that required 4 hospitalizations for intensive medical and interventional treatment. Between VT storms, he remained comfortable. On his third hospitalization for recurrent VT, the admitting team suggested that the ICD be turned off. The next day Mr. C, his wife, and I had an hour-long discussion about his options. I was reluctant to turn off the ICD because I was convinced that the VT storms could be effectively controlled while minimizing the need for ICD shocks. He was otherwise still a functional, active man.

Mr. C agreed, but we drew a clear outline of resuscitative interventions (living will, DNR orders). His VT was indeed effectively treated, but he became pacemaker reliant. We planned an upgrade to triple-chamber CRT ICD pending resolution of prostate-related urinary retention.

The required urological surgical interventions dampened Mr. C's enthusiasm for further procedures, and he delayed his ICD upgrade for several months, all the while accepting the decreased cardiac functionality that accompanies nonsynchronous single-chamber right ventricular pacing. He finally was admitted for congestive heart failure exacerbation in early April 2011, and upgrade surgery was scheduled. In preparation, he received an acetylcysteine pill. He was comfortably sitting up in bed without dyspnea, talking and joking, yet he choked on his pill and somehow, inexplicably, proceeded to have a sudden cardiorespiratory arrest (due to pulseless electrical activity without intervening VT or VF). A code blue was quickly called off in accordance with his expressed and documented living will wishes.

In summary, Mr. C's up close and personal experience with his ICD was short lived and unpleasant, but the device intervened as necessary to treat his VT while he was still functional. Further, it allowed him to face his mortality and make peace with it as well as put his affairs in order prior to passing. Would he have been better off taking the earlier advice to turn off his ICD? Perhaps not, as his last 4 months were less active but, by all accounts, reasonably content.

Mr. and Mrs. Butler

Elsewhere in this issue, Lisa Tompkins discusses Mrs. Valerie Butler's struggles to have her husband's pacemaker turned off. He had been implanted with the pacemaker a few years earlier for asymptomatic bradycardia. He was now suffering from a debilitating but chronic illness. His physician refused to turn the pacemaker off for fear of precipitating Mr. Butler's immediate death. Despite multiple attempts, Mrs. Butler found no one else to turn to for help to deactivate the pacemaker. Mr. Butler continued living a diminished life for another 3 years.

Mr. Butler's physician's refusal to deactivate the pacemaker is anathema to the principles discussed in this paper. However, it seems that Mr. Butler was not pacemaker dependent. Therefore, turning the pacemaker off would not have accelerated his death. Deactivation may have changed nothing or, worse, may have carried the risk of further reducing his quality of life. This scenario, in my opinion, did not seem to have been well described to Mr. Butler's family.

This case underscores the impact of ineffective communication on the welfare of both patients and their families alike. As a result of her husband's experience, Mrs. Butler's views about medical interventions may have become excessively polarized. Consequently, when she developed a need for valve surgery, she may have been less inclined to frame a working compromise with her appointed surgeon as to perioperative do-not-resuscitate status. She ended up declining surgery, thus likely curtailing both the duration and quality of her remaining life.

CONCLUSIONS

In summary, CIEDs offer many beneficial therapeutic interventions. Under ideal conditions, they simultaneously prolong life and improve its quality.

When death from any cause seems to be imminent, CIEDs may complicate the process of dying. Under these circumstances, thoughtful consideration should be given to turning off some or all of the features of these sophisticated devices.

Patients may be unaware of the feasibility of CIED inactivation, or they may have difficulty articulating their stance and wishes vis à vis end-of-life CIED management. It therefore behooves physicians who deal with CIED patients to initiate these discussions well in advance. In my view, device deactivation options—especially for ICDs—should be detailed during the preimplantation informed consent process.

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